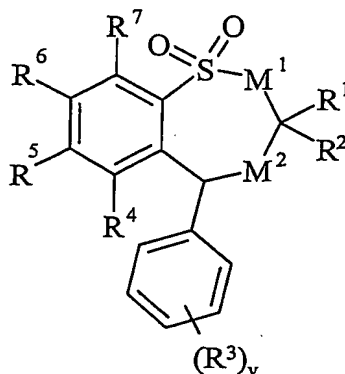


Claims

1. A compound of formula (I):



(I)

wherein

$M^1$  is  $-CH_2-$  or  $-NR^{21}-$ ;

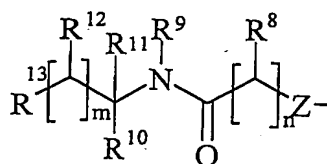
$M^2$  is  $-CR^{22}R^{23}-$  or  $-NR^{24}-$ ; provided that if  $M^1$  is  $-NR^{21}-$ ,  $M^2$  is  $-CR^{22}R^{23}-$ ;

One of  $R^1$  and  $R^2$  are selected from hydrogen,  $C_{1-6}$ alkyl or  $C_{2-6}$ alkenyl and the other is  
10 selected from  $C_{1-6}$ alkyl or  $C_{2-6}$ alkenyl;

$R^3$  is selected from halo, nitro, cyano, hydroxy, amino, carboxy, carbamoyl, mercapto, sulphamoyl,  $C_{1-6}$ alkyl,  $C_{2-6}$ alkenyl,  $C_{2-6}$ alkynyl,  $C_{1-6}$ alkoxy,  $C_{1-6}$ alkanoyl,  $C_{1-6}$ alkanoyloxy,  $N-(C_{1-6}alkyl)amino$ ,  $N,N-(C_{1-6}alkyl)_2amino$ ,  $C_{1-6}alkanoylamino$ ,  $N-(C_{1-6}alkyl)carbamoyl$ ,  $N,N-(C_{1-6}alkyl)_2carbamoyl$ ,  $C_{1-6}alkylS(O)_a$  wherein  $a$  is 0 to 2,  $C_{1-6}alkoxycarbonyl$ ,  
15  $N-(C_{1-6}alkyl)sulphamoyl$  and  $N,N-(C_{1-6}alkyl)_2sulphamoyl$ ;

$v$  is 0-5;

one of  $R^5$  and  $R^6$  is a group of formula (IA):



(IA)

20  $R^4$  and  $R^7$  and the other of  $R^5$  and  $R^6$  are independently selected from hydrogen, halo, nitro, cyano, hydroxy, amino, carboxy, carbamoyl, mercapto, sulphamoyl,  $C_{1-4}$ alkyl,  $C_{2-4}$ alkenyl,  $C_{2-4}$ alkynyl,  $C_{1-4}$ alkoxy,  $C_{1-4}$ alkanoyl,  $C_{1-4}$ alkanoyloxy,  $N-(C_{1-4}alkyl)amino$ ,  $N,N-(C_{1-4}alkyl)_2amino$ ,  $C_{1-4}alkanoylamino$ ,  $N-(C_{1-4}alkyl)carbamoyl$ ,

*N,N*-(C<sub>1-4</sub>alkyl)<sub>2</sub>carbamoyl, C<sub>1-4</sub>alkylS(O)<sub>a</sub> wherein a is 0 to 2, C<sub>1-4</sub>alkoxycarbonyl, *N*-(C<sub>1-4</sub>alkyl)sulphamoyl and *N,N*-(C<sub>1-4</sub>alkyl)<sub>2</sub>sulphamoyl; wherein R<sup>4</sup> and R<sup>7</sup> and the other of R<sup>5</sup> and R<sup>6</sup> may be optionally substituted on carbon by one or more R<sup>25</sup>;

Z is -O-, -N(R<sup>a</sup>)-, -S(O)<sub>b</sub>- or -CH(R<sup>a</sup>)-; wherein R<sup>a</sup> is hydrogen or C<sub>1-6</sub>alkyl and b is 0-5 2;

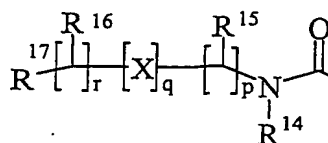
R<sup>8</sup> is hydrogen, C<sub>1-4</sub>alkyl, carbocyclyl or heterocyclyl; wherein R<sup>8</sup> may be optionally substituted on carbon by one or more substituents selected from R<sup>26</sup>; and wherein if said heterocyclyl contains an -NH- group, that nitrogen may be optionally substituted by a group selected from R<sup>27</sup>;

10 R<sup>9</sup> is hydrogen or C<sub>1-4</sub>alkyl;

R<sup>10</sup> and R<sup>11</sup> are independently selected from hydrogen, C<sub>1-4</sub>alkyl, carbocyclyl or heterocyclyl; or R<sup>10</sup> and R<sup>11</sup> together form C<sub>2-6</sub>alkylene; wherein R<sup>10</sup> and R<sup>11</sup> or R<sup>10</sup> and R<sup>11</sup> together may be independently optionally substituted on carbon by one or more substituents selected from R<sup>28</sup>; and wherein if said heterocyclyl contains an -NH- moiety, that nitrogen  
15 may be optionally substituted by one or more R<sup>29</sup>;

R<sup>12</sup> is hydrogen, C<sub>1-4</sub>alkyl, carbocyclyl or heterocyclyl; wherein R<sup>12</sup> may be optionally substituted on carbon by one or more substituents selected from R<sup>30</sup>; and wherein if said heterocyclyl contains an -NH- moiety, that nitrogen may be optionally substituted by one or more R<sup>31</sup>;

20 R<sup>13</sup> is hydrogen, halo, nitro, cyano, hydroxy, amino, carbamoyl, mercapto, sulphamoyl, hydroxyaminocarbonyl, C<sub>1-10</sub>alkyl, C<sub>2-10</sub>alkenyl, C<sub>2-10</sub>alkynyl, C<sub>1-10</sub>alkoxy, C<sub>1-10</sub>alkoxycarbonyl, C<sub>1-10</sub>alkanoyl, C<sub>1-10</sub>alkanoyloxy, *N*-(C<sub>1-10</sub>alkyl)amino, *N,N*-(C<sub>1-10</sub>alkyl)<sub>2</sub>amino, *N,N,N*-(C<sub>1-10</sub>alkyl)<sub>3</sub>ammonio, C<sub>1-10</sub>alkanoylamino, *N*-(C<sub>1-10</sub>alkyl)carbamoyl, *N,N*-(C<sub>1-10</sub>alkyl)<sub>2</sub>carbamoyl, C<sub>1-10</sub>alkylS(O)<sub>a</sub> wherein a is 0 to 2,  
25 *N*-(C<sub>1-10</sub>alkyl)sulphamoyl, *N,N*-(C<sub>1-10</sub>alkyl)<sub>2</sub>sulphamoyl, *N*-(C<sub>1-10</sub>alkyl)sulphamoylamino, *N,N*-(C<sub>1-10</sub>alkyl)<sub>2</sub>sulphamoylamino, C<sub>1-10</sub>alkoxycarbonylamino, carbocyclyl, carbocyclylC<sub>1-10</sub>alkyl, heterocyclic group, heterocyclylC<sub>1-10</sub>alkyl, carbocyclyl-(C<sub>1-10</sub>alkylene)<sub>e</sub>-R<sup>32</sup>-(C<sub>1-10</sub>alkylene)<sub>f</sub> or heterocyclyl-(C<sub>1-10</sub>alkylene)<sub>g</sub>-R<sup>33</sup>-(C<sub>1-10</sub>alkylene)<sub>h</sub>; wherein R<sup>13</sup> may be optionally substituted  
30 on carbon by one or more substituents selected from R<sup>36</sup>; and wherein if said heterocyclyl contains an -NH- group, that nitrogen may be optionally substituted by a group selected from R<sup>37</sup>; or R<sup>13</sup> is a group of formula (IB):



(IB)

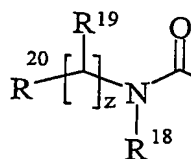
wherein:

X is  $-\text{N}(\text{R}^{38})-$ ,  $-\text{N}(\text{R}^{38})\text{C}(\text{O})-$ ,  $-\text{O}-$ , and  $-\text{S}(\text{O})_a-$ ; wherein a is 0-2 and  $\text{R}^{38}$  is hydrogen or  
5  $\text{C}_{1-4}$ alkyl;

$\text{R}^{14}$  is hydrogen or  $\text{C}_{1-4}$ alkyl;

$\text{R}^{15}$  and  $\text{R}^{16}$  are independently selected from hydrogen, halo, nitro, cyano, hydroxy, amino, carbamoyl, mercapto, sulphamoyl,  $\text{C}_{1-6}$ alkyl,  $\text{C}_{2-6}$ alkenyl,  $\text{C}_{2-6}$ alkynyl,  $\text{C}_{1-6}$ alkoxy,  $\text{C}_{1-6}$ alkanoyl,  $\text{C}_{1-6}$ alkanoyloxy,  $N$ -( $\text{C}_{1-6}$ alkyl)amino,  $N,N$ -( $\text{C}_{1-6}$ alkyl)<sub>2</sub>amino,  
10  $\text{C}_{1-6}$ alkanoylamino,  $N$ -( $\text{C}_{1-6}$ alkyl)carbamoyl,  $N,N$ -( $\text{C}_{1-6}$ alkyl)<sub>2</sub>carbamoyl,  $\text{C}_{1-6}$ alkylS(O)<sub>a</sub> wherein a is 0 to 2,  $\text{C}_{1-6}$ alkoxycarbonyl,  $N$ -( $\text{C}_{1-6}$ alkyl)sulphamoyl,  $N,N$ -( $\text{C}_{1-6}$ alkyl)<sub>2</sub>sulphamoyl, carbocyclyl or heterocyclic group; wherein  $\text{R}^{15}$  and  $\text{R}^{16}$  may be independently optionally substituted on carbon by one or more substituents selected from  $\text{R}^{41}$ ; and wherein if said heterocyclyl contains an -NH- group, that nitrogen may be optionally substituted by a group  
15 selected from  $\text{R}^{42}$ ;

$\text{R}^{17}$  is selected from hydrogen, halo, nitro, cyano, hydroxy, amino, carbamoyl, mercapto, sulphamoyl, hydroxyaminocarbonyl,  $\text{C}_{1-10}$ alkyl,  $\text{C}_{2-10}$ alkenyl,  $\text{C}_{2-10}$ alkynyl,  $\text{C}_{1-10}$ alkoxy,  $\text{C}_{1-10}$ alkanoyl,  $\text{C}_{1-10}$ alkanoyloxy,  $N$ -( $\text{C}_{1-10}$ alkyl)amino,  $N,N$ -( $\text{C}_{1-10}$ alkyl)<sub>2</sub>amino,  $\text{C}_{1-10}$ alkanoylamino,  $N$ -( $\text{C}_{1-10}$ alkyl)carbamoyl,  $\text{C}_{1-10}$ alkoxycarbonyl,  
20  $N,N$ -( $\text{C}_{1-10}$ alkyl)<sub>2</sub>carbamoyl,  $\text{C}_{1-10}$ alkylS(O)<sub>a</sub> wherein a is 0 to 2,  $N$ -( $\text{C}_{1-10}$ alkyl)sulphamoyl,  $N,N$ -( $\text{C}_{1-10}$ alkyl)<sub>2</sub>sulphamoyl,  $N$ -( $\text{C}_{1-10}$ alkyl)sulphamoylamino,  $N,N$ -( $\text{C}_{1-10}$ alkyl)<sub>2</sub>sulphamoylamino, carbocyclyl, carbocyclyl $\text{C}_{1-10}$ alkyl, heterocyclic group, heterocyclyl $\text{C}_{1-10}$ alkyl, carbocyclyl-( $\text{C}_{1-10}$ alkylene)<sub>e</sub>- $\text{R}^{43}$ -( $\text{C}_{1-10}$ alkylene)<sub>f</sub> or heterocyclyl-( $\text{C}_{1-10}$ alkylene)<sub>g</sub>- $\text{R}^{44}$ -( $\text{C}_{1-10}$ alkylene)<sub>h</sub>; wherein  $\text{R}^{17}$  may be optionally substituted  
25 on carbon by one or more substituents selected from  $\text{R}^{47}$ ; and wherein if said heterocyclyl contains an -NH- group, that nitrogen may be optionally substituted by a group selected from  $\text{R}^{48}$ ; or  $\text{R}^{17}$  is a group of formula (IC):



(IC)

wherein:

$R^{18}$  is selected from hydrogen or  $C_{1-4}$ alkyl;

- 5  $R^{19}$  is selected from hydrogen, halo, nitro, cyano, hydroxy, amino, carbamoyl, mercapto, sulphamoyl,  $C_{1-6}$ alkyl,  $C_{2-6}$ alkenyl,  $C_{2-6}$ alkynyl,  $C_{1-6}$ alkoxy,  $C_{1-6}$ alkanoyl,  $C_{1-6}$ alkanoyloxy,  $N$ -( $C_{1-6}$ alkyl)amino,  $N,N$ -( $C_{1-6}$ alkyl)<sub>2</sub>amino,  $C_{1-6}$ alkanoylamino,  $N$ -( $C_{1-6}$ alkyl)carbamoyl,  $N,N$ -( $C_{1-6}$ alkyl)<sub>2</sub>carbamoyl,  $C_{1-6}$ alkylS(O)<sub>a</sub> wherein a is 0 to 2,  $C_{1-6}$ alkoxycarbonyl,  $N$ -( $C_{1-6}$ alkyl)sulphamoyl,  $N,N$ -( $C_{1-6}$ alkyl)<sub>2</sub>sulphamoyl, carbocyclyl or
- 10 heterocyclic group; where  $R^{19}$  may be independently optionally substituted on carbon by one or more substituents selected from  $R^{51}$ ; and wherein if said heterocyclyl contains an -NH- group, that nitrogen may be optionally substituted by a group selected from  $R^{52}$ ;

- $R^{20}$  is selected from halo, nitro, cyano, hydroxy, amino, carbamoyl, mercapto, sulphamoyl, hydroxyaminocarbonyl,  $C_{1-10}$ alkyl,  $C_{2-10}$ alkenyl,  $C_{2-10}$ alkynyl,  $C_{1-10}$ alkoxy,  $C_{1-10}$ alkoxycarbonyl,  $C_{1-10}$ alkanoyl,  $C_{1-10}$ alkanoyloxy,  $N$ -( $C_{1-10}$ alkyl)amino,  $N,N$ -( $C_{1-10}$ alkyl)<sub>2</sub>amino,  $N,N,N$ -( $C_{1-10}$ alkyl)<sub>3</sub>ammonio,  $C_{1-10}$ alkanoylamino,  $N$ -( $C_{1-10}$ alkyl)carbamoyl,  $N,N$ -( $C_{1-10}$ alkyl)<sub>2</sub>carbamoyl,  $C_{1-10}$ alkylS(O)<sub>a</sub> wherein a is 0 to 2,  $N$ -( $C_{1-10}$ alkyl)sulphamoyl,  $N,N$ -( $C_{1-10}$ alkyl)<sub>2</sub>sulphamoyl,  $N$ -( $C_{1-10}$ alkyl)sulphamoylamino,  $N,N$ -( $C_{1-10}$ alkyl)<sub>2</sub>sulphamoylamino,  $C_{1-10}$ alkoxycarbonylamino, carbocyclyl,
- 15 carbocyclyl $C_{1-10}$ alkyl, heterocyclic group, heterocyclyl $C_{1-10}$ alkyl, carbocyclyl-( $C_{1-10}$ alkylene)<sub>e</sub>- $R^{53}$ -( $C_{1-10}$ alkylene)<sub>f</sub> or heterocyclyl-( $C_{1-10}$ alkylene)<sub>g</sub>- $R^{54}$ -( $C_{1-10}$ alkylene)<sub>h</sub>; wherein  $R^{20}$  may be independently optionally substituted on carbon by one or more  $R^{57}$ ; and wherein if said heterocyclyl contains an -NH- group, that nitrogen may be optionally substituted by a group selected from  $R^{58}$ ;

- 25 p is 1-3; wherein the values of  $R^{15}$  may be the same or different;

q is 0-1;

r is 0-3; wherein the values of  $R^{16}$  may be the same or different;

m is 0-2; wherein the values of  $R^{12}$  may be the same or different;

n is 1-2; wherein the values of  $R^8$  may be the same or different;

- 30 z is 0-3; wherein the values of  $R^{19}$  may be the same or different;

$R^{21}$  is selected from hydrogen or  $C_{1-6}$ alkyl;

$R^{22}$  and  $R^{23}$  are independently selected from hydrogen, hydroxy, amino, mercapto,  $C_{1-6}$ alkyl,  $C_{1-6}$ alkoxy,  $N$ -( $C_{1-6}$ alkyl)amino,  $N,N$ -( $C_{1-6}$ alkyl)<sub>2</sub>amino,  $C_{1-6}$ alkylS(O)<sub>a</sub> wherein a is 0 to 2;

5  $R^{24}$  is selected from hydrogen, hydroxy,  $C_{1-6}$ alkyl,  $C_{1-4}$ alkoxy and  $C_{1-6}$ alkanoyloxy;

$R^{25}$  is selected from halo, nitro, cyano, hydroxy, amino, carboxy, carbamoyl, mercapto, sulphamoyl,  $C_{1-4}$ alkyl,  $C_{2-4}$ alkenyl,  $C_{2-4}$ alkynyl,  $C_{1-4}$ alkoxy,  $C_{1-4}$ alkanoyl,  $C_{1-4}$ alkanoyloxy,  $N$ -( $C_{1-4}$ alkyl)amino,  $N,N$ -( $C_{1-4}$ alkyl)<sub>2</sub>amino,  $C_{1-4}$ alkanoylamino,  $N$ -( $C_{1-4}$ alkyl)carbamoyl,  $N,N$ -( $C_{1-4}$ alkyl)<sub>2</sub>carbamoyl,  $C_{1-4}$ alkylS(O)<sub>a</sub> wherein a is 0 to 2,  $C_{1-4}$ alkoxycarbonyl,

10  $N$ -( $C_{1-4}$ alkyl)sulphamoyl and  $N,N$ -( $C_{1-4}$ alkyl)<sub>2</sub>sulphamoyl; wherein  $R^{25}$ , may be independently optionally substituted on carbon by one or more  $R^{67}$ ;

$R^{26}$ ,  $R^{28}$ ,  $R^{30}$ ,  $R^{36}$ ,  $R^{41}$ ,  $R^{47}$ ,  $R^{51}$  and  $R^{57}$  are independently selected from halo, nitro, cyano, hydroxy, amino, carbamoyl, mercapto, sulphamoyl, hydroxyaminocarbonyl,  $C_{1-10}$ alkyl,  $C_{2-10}$ alkenyl,  $C_{2-10}$ alkynyl,  $C_{1-10}$ alkoxy,  $C_{1-10}$ alkanoyl,  $C_{1-10}$ alkanoyloxy,  $C_{1-10}$ alkoxycarbonyl,

15  $N$ -( $C_{1-10}$ alkyl)amino,  $N,N$ -( $C_{1-10}$ alkyl)<sub>2</sub>amino,  $N,N,N$ -( $C_{1-10}$ alkyl)<sub>3</sub>ammonio,  $C_{1-10}$ alkanoylamino,  $N$ -( $C_{1-10}$ alkyl)carbamoyl,  $N,N$ -( $C_{1-10}$ alkyl)<sub>2</sub>carbamoyl,  $C_{1-10}$ alkylS(O)<sub>a</sub> wherein a is 0 to 2,  $N$ -( $C_{1-10}$ alkyl)sulphamoyl,  $N,N$ -( $C_{1-10}$ alkyl)<sub>2</sub>sulphamoyl,  $N$ -( $C_{1-10}$ alkyl)sulphamoylamino,  $N,N$ -( $C_{1-10}$ alkyl)<sub>2</sub>sulphamoylamino,  $C_{1-10}$ alkoxycarbonylamino, carbocyclyl, carbocyclyl $C_{1-10}$ alkyl, heterocyclic group,

20 heterocyclyl $C_{1-10}$ alkyl, carbocyclyl-( $C_{1-10}$ alkylene)<sub>e</sub>- $R^{59}$ -( $C_{1-10}$ alkylene)<sub>f</sub> or heterocyclyl-( $C_{1-10}$ alkylene)<sub>g</sub>- $R^{60}$ -( $C_{1-10}$ alkylene)<sub>h</sub>; wherein  $R^{26}$ ,  $R^{28}$ ,  $R^{30}$ ,  $R^{36}$ ,  $R^{41}$ ,  $R^{47}$ ,  $R^{51}$  and  $R^{57}$  may be independently optionally substituted on carbon by one or more  $R^{63}$ ; and wherein if said heterocyclyl contains an -NH- group, that nitrogen may be optionally substituted by a group selected from  $R^{64}$ ;

25  $R^{27}$ ,  $R^{29}$ ,  $R^{31}$ ,  $R^{37}$ ,  $R^{42}$ ,  $R^{48}$ ,  $R^{52}$ ,  $R^{58}$  and  $R^{64}$  are independently selected from  $C_{1-6}$ alkyl,  $C_{1-6}$ alkanoyl,  $C_{1-6}$ alkylsulphonyl, sulphamoyl,  $N$ -( $C_{1-6}$ alkyl)sulphamoyl,  $N,N$ -( $C_{1-6}$ alkyl)<sub>2</sub>sulphamoyl,  $C_{1-6}$ alkoxycarbonyl, carbamoyl,  $N$ -( $C_{1-6}$ alkyl)carbamoyl,  $N,N$ -( $C_{1-6}$ alkyl)<sub>2</sub>carbamoyl, benzyl, phenethyl, benzoyl, phenylsulphonyl and phenyl;

$R^{32}$ ,  $R^{33}$ ,  $R^{43}$ ,  $R^{44}$ ,  $R^{53}$ ,  $R^{54}$ ,  $R^{59}$  and  $R^{60}$  are independently selected from -O-, - $NR^{65}$ -,  
30 -S(O)<sub>x</sub>-, - $NR^{65}C(O)NR^{66}$ -, - $NR^{65}C(S)NR^{66}$ -, -OC(O)N=C-, - $NR^{65}C(O)$ - or -C(O) $NR^{65}$ -; wherein  $R^{65}$  and  $R^{66}$  are independently selected from hydrogen or  $C_{1-6}$ alkyl, and x is 0-2;

$R^{63}$  and  $R^{67}$  are independently selected from halo, hydroxy, cyano, carbamoyl, ureido, amino, nitro, carbamoyl, mercapto, sulphamoyl, trifluoromethyl, trifluoromethoxy, methyl, ethyl, methoxy, ethoxy, vinyl, allyl, ethynyl, methoxycarbonyl, formyl, acetyl, formamido, acetylamino, acetoxy, methylamino, dimethylamino, *N*-methylcarbamoyl,

- 5 *N,N*-dimethylcarbamoyl, methylthio, methylsulphinyl, mesyl, *N*-methylsulphamoyl and *N,N*-dimethylsulphamoyl; and

*e*, *f*, *g* and *h* are independently selected from 0-2;

or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof.

- 10 2. A compound of formula (I) according to claim 1 wherein  $M^1$  is  $-CH_2-$  and  $M^2$  is  $-CR^{22}R^{23}-$ ; or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof.

3. A compound of formula (I) according to claim 1 wherein  $M^1$  is  $-CH_2-$  and  $M^2$  is  $-NR^{24}-$ ; or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof.

4. A compound of formula (I) according to claim 1 or 2 wherein  $R^{22}$  and  $R^{23}$  are independently selected from hydrogen and hydroxy; or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof.

5. A compound of formula (I) according to claim 1 or 3 wherein  $R^{24}$  is hydrogen; or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof.

- 25 6. A compound of formula (I) according to any one of claims 1-5 wherein  $R^1$  and  $R^2$  are  $C_{1-4}$ alkyl; or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof.

7. A compound of formula (I) according to any one of claims 1-6 wherein *v* is 0; or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof.

8. A compound of formula (I) according to any one of claims 1-7 wherein  $R^4$  and  $R^7$  are hydrogen; or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof;
- 5 9. A compound of formula (I) according to any one of claims 1-8 wherein the  $R^5$  or  $R^6$  not selected from a group of formula (IA) is hydrogen or methylthio; or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof.
10. A compound of formula (I) according to any one of claims 1-9 wherein one of  $R^5$  and
- 10  $R^6$  is a group of formula (IA) (as depicted above); wherein:
- $Z$  is -O- or -S(O)<sub>b</sub>-; wherein  $b$  is 0;
- $R^8$  is hydrogen;
- $R^9$  is hydrogen;
- $R^{10}$  and  $R^{11}$  are independently selected from hydrogen or carbocyclyl; wherein  $R^{10}$  and
- 15  $R^{11}$  may be independently optionally substituted on carbon by one or more substituents selected from  $R^{28}$ ;
- $R^{13}$  is a group of formula (IB) (as depicted above);
- $R^{14}$  is hydrogen;
- $R^{15}$  is hydrogen;
- 20  $R^{17}$  is C<sub>1-10</sub>alkyl; wherein  $R^{17}$  may be optionally substituted on carbon by one or more substituents selected from  $R^{47}$ ; or  $R^{17}$  is a group of formula (IC) (as depicted above) wherein:
- $R^{18}$  is selected from hydrogen;
- $R^{19}$  is selected from hydrogen;
- $R^{20}$  is C<sub>1-10</sub>alkyl; wherein  $R^{20}$  may be independently optionally substituted on carbon
- 25 by one or more  $R^{57}$ ;
- $p$  is 1;
- $q$  is 0;
- $r$  is 0;
- $m$  is 0;
- 30  $n$  is 1;
- $z$  is 1; and
- $R^{28}$ ,  $R^{47}$  and  $R^{57}$  are independently selected from halo and hydroxy

or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof.

11. A compound of formula (I) wherein:

$M^1$  is  $-\text{CH}_2-$ ;

5  $M^2$  is  $-\text{CR}^{22}\text{R}^{23}-$  and  $-\text{NR}^{24}-$ ;

$\text{R}^{22}$  and  $\text{R}^{23}$  are independently selected from hydrogen and hydroxy;

One of  $\text{R}^1$  and  $\text{R}^2$  is ethyl and the other is butyl;

$v$  is 0;

$\text{R}^4$  and  $\text{R}^7$  are hydrogen;

10 One of  $\text{R}^5$  or  $\text{R}^6$  is selected from a group of formula (IA) (as depicted above) and the other is hydrogen or methylthio;

$\text{Z}$  is  $-\text{O}-$  or  $-\text{S}(\text{O})_b-$ ; wherein  $b$  is 0;

$\text{R}^8$  is hydrogen;

$\text{R}^9$  is hydrogen;

15  $\text{R}^{10}$  and  $\text{R}^{11}$  are independently selected from hydrogen, 2-fluorophenyl or carbocyclyl;

$\text{R}^{13}$  is a group of formula (IB) (as depicted above);

$\text{R}^{14}$  is hydrogen;

$\text{R}^{15}$  is hydrogen;

20  $\text{R}^{17}$  is pentyl substituted by 5 hydroxy; or  $\text{R}^{17}$  is a group of formula (IC) (as depicted above) wherein:

$\text{R}^{18}$  is selected from hydrogen;

$\text{R}^{19}$  is selected from hydrogen;

$\text{R}^{20}$  is pentyl substituted by 5 hydroxy;

$p$  is 1;

25  $q$  is 0;

$r$  is 0;

$m$  is 0;

$n$  is 1; and

$z$  is 1;

30 or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof.

12. A compound of formula (I) selected from:



(+/-)-trans-1,1-dioxo-3-ethyl-3-butyl-5-phenyl-7-methylthio-8-(N-{(R)- $\alpha$ -[N'-(2-(S)-3-(R)-4-(R)-5-(R)-2,3,4,5,6-pentahydroxyhexyl)carbamoyl]benzyl}carbamoylmethoxy)-2,3,4,5-tetrahydro-1,4-benzothiazepine;

(+/-)-trans-1,1-dioxo-3-ethyl-3-butyl-5-phenyl-7-methylthio-8-(N-{(R)- $\alpha$ -[N'-(2-(S)-3-(R)-4-(R)-5-(R)-2,3,4,5,6-pentahydroxyhexyl)carbamoyl]benzyl}carbamoylmethoxy)-2,3,4,5-tetrahydro-1,4-benzothiazepine;

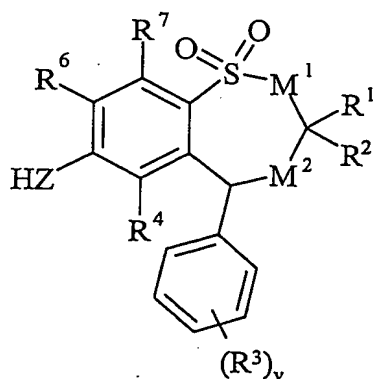
1,1-dioxo-3-ethyl-3-butyl-4-hydroxy-5-phenyl-7-(N-{ $\alpha$ -[N'-(2-(S)-3-(R)-4-(R)-5-(R)-2,3,4,5,6-pentahydroxyhexyl)carbamoyl]-2-fluorobenzyl}carbamoylmethylthio)-2,3,4,5-tetrahydrobenzothiepine; or

10 1,1-dioxo-3-butyl-3-ethyl-4-hydroxy-5-phenyl-7-(N-{1-[N'-(2-(S)-3-(R)-4-(R)-5-(R)-2,3,4,5,6-pentahydroxyhexyl)carbamoyl]-1-(cyclohexyl)methyl}carbamoylmethylthio)-2,3,4,5-tetrahydrobenzothiepine;

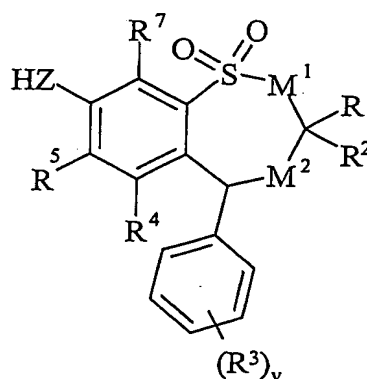
or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof.

15 13. A process for preparing a compound of formula (I) or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof, as claimed in anyone of claims 1-12, which process (wherein variable groups are, unless otherwise specified, as defined in claim 1) comprises of:

*Process 1*): for compounds of formula (I) wherein Z is -O-, -NR<sup>a</sup> or -S-; reacting a compound  
20 of formula (IIa) or (IIb):

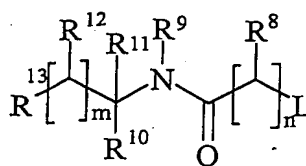


(IIa)



(IIb)

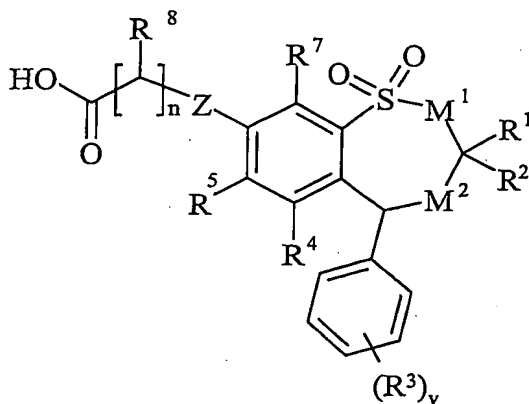
with a compound of formula (III):



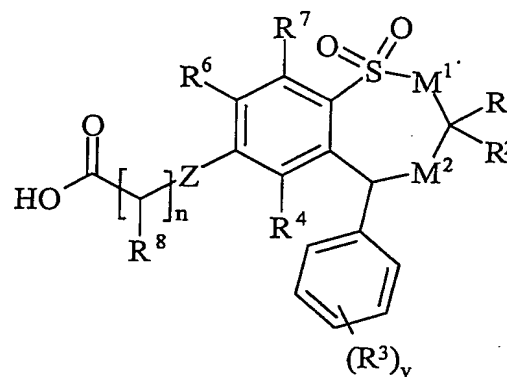
(III)

wherein L is a displaceable group;

Process 2): reacting an acid of formula (IVa) or (IVb):

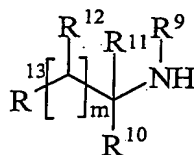


(IVa)



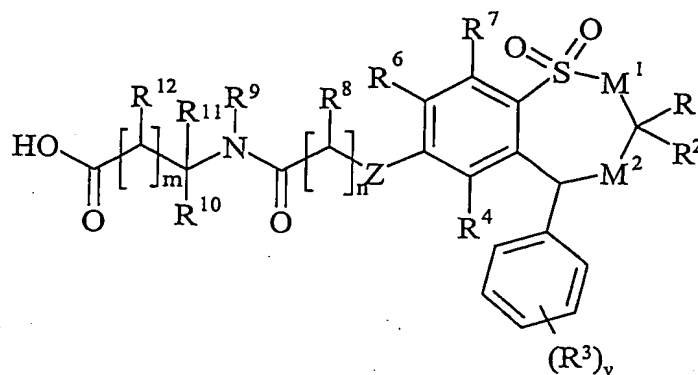
(IVb)

or an activated derivative thereof; with an amine of formula (V):



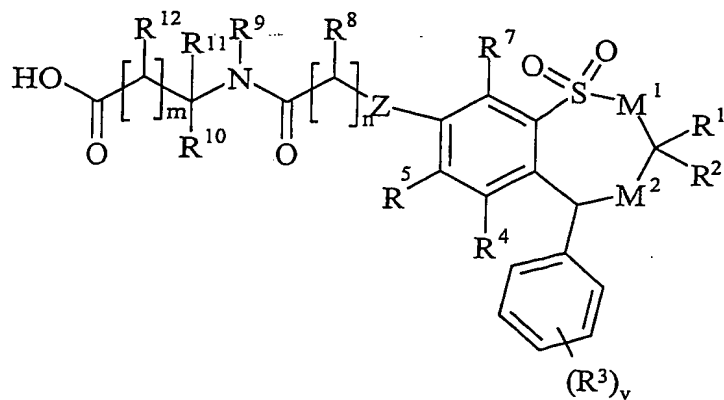
(V);

10 Process 3): for compounds of formula (I) wherein R<sup>13</sup> is a group of formula (IB); reacting an acid of formula (VIa):



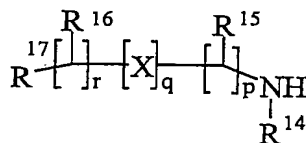
(VIa)

or (VIb):



(VIb)

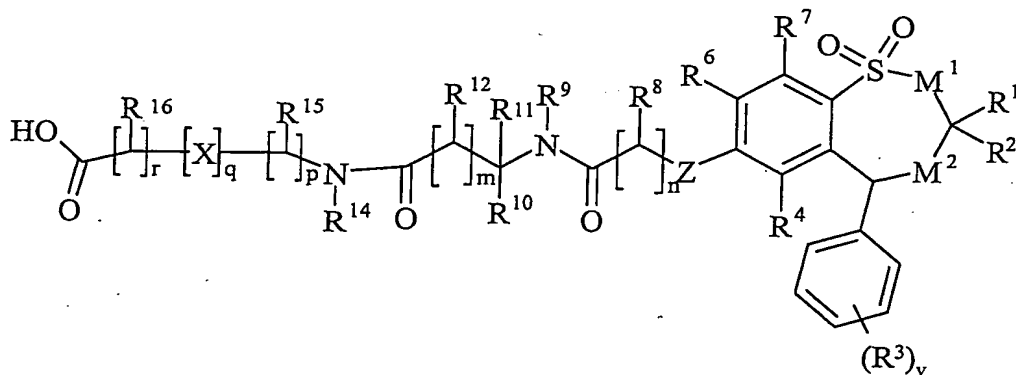
with an amine of formula:



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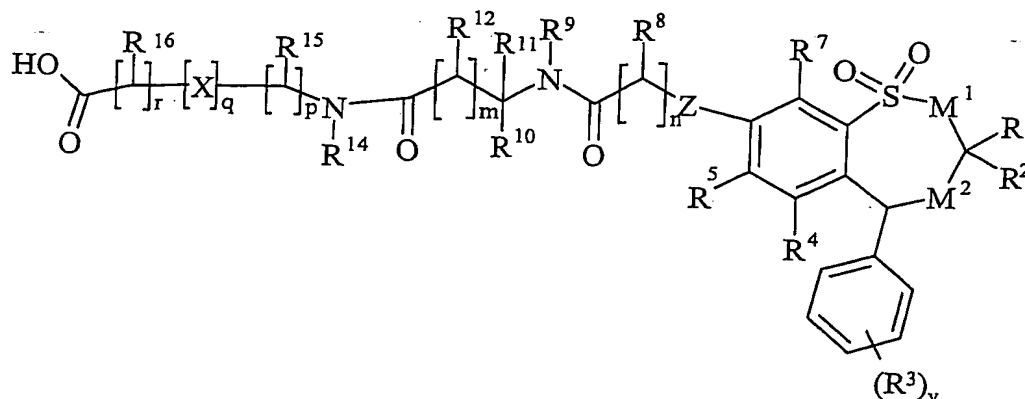
(VI)

*Process 4*): for compounds of formula (I) wherein  $R^{13}$  is a group of formula (IB) and  $R^{17}$  is a group of formula (IC); reacting an acid of formula (VIIIa):



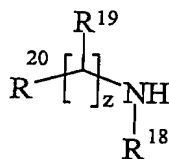
(VIIIa)

10 or (VIIIb)



(VIIIb)

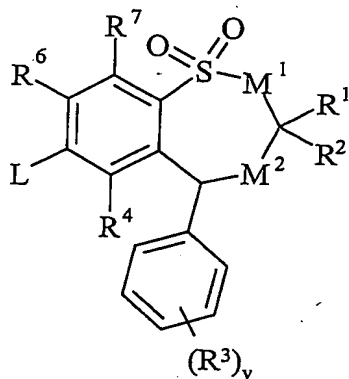
or an activated derivative thereof; with an amine of formula (IX):



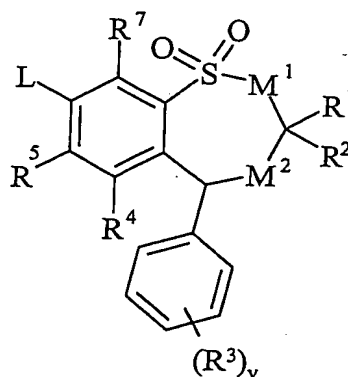
(IX)

5

*Process 5*) for compounds of formula (I) wherein one of R<sup>5</sup> and R<sup>6</sup> are independently selected from C<sub>1-6</sub>alkylthio optionally substituted on carbon by one or more R<sup>25</sup>; reacting a compound of formula (Xa) or (Xb):



(Xa)



(Xb)

10

wherein L is a displaceable group; with a thiol of formula (XI):



(XI)

wherein R<sup>m</sup> is C<sub>1-6</sub>alkylthio optionally substituted on carbon by one or more R<sup>25</sup>;

15 and thereafter if necessary or desirable:

i) converting a compound of the formula (I) into another compound of the formula (I);

- ii) removing any protecting groups;
- iii) forming a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug.

14. A compound of the formula (I), or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof, as claimed in any one of claims 1 to 12 for use as a medicament.

15. A compound of formula (I), or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof, as claimed in any one of claims 1 to 12 for use in a method of prophylactic or therapeutic treatment of a warm-blooded animal, such as man.

16. The use of a compound of the formula (I), or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof, as claimed in any one of claims 1 to 12 in the manufacture of a medicament for use in the production of an IBAT inhibitory effect in a warm-blooded animal, such as man.

17. A method for producing an IBAT inhibitory effect in a warm-blooded animal, such as man, in need of such treatment which comprises administering to said animal an effective amount of a compound of formula (I), or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof, as claimed in any one of claims 1 to 12.

18. A pharmaceutical composition which comprises a compound of formula (I), or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof, as claimed in any one of claims 1 to 12, in association with a pharmaceutically-acceptable diluent or carrier.

19. A combination comprising a compound of formula (I), or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof, as claimed in any one of claims 1 to 12, and an HMG Co-A reductase inhibitor, or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof.

20. A combination comprising a compound of formula (I), or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof, as claimed in any one of claims 1 to 12, and a bile acid binder.

5 21. A combination comprising a compound of formula (I), or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof, as claimed in any one of claims 1 to 12, and an HMG Co-A reductase inhibitor, or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof, and a bile acid binder.

10 22. A combination according to claim 19 or claim 21 wherein the HMG Co-A reductase inhibitor is atorvastatin, or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof.

23. A combination according to claim 19 or claim 21 wherein the HMG Co-A reductase  
15 inhibitor is rosuvastatin, or a pharmaceutically acceptable salt thereof.

24. A combination comprising a compound of formula (I), or a pharmaceutically acceptable salt, solvate, solvate of such a salt or a prodrug thereof, as claimed in any one of claims 1 to 12 and a PPAR alpha and/or gamma agonist, or a pharmaceutically acceptable salt  
20 thereof.

25. A composition according to claim 24 wherein the PPAR alpha and/or gamma agonist is (S)-2-ethoxy-3-[4-(2-{4-methanesulphonyloxyphenyl}ethoxy)phenyl]propanoic acid or a pharmaceutically acceptable salt thereof.

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